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REMARKS

Claims 5-15 have been cancelled from the application, and new claims 16-37 have been substituted therefore. No new matter has been added. It is to be noted that claims 5-15 have not been canceled for purposes relating to patentability. Rather, claims 16-37 are being substituted for claims 5-15 for purposes of clarification, and in order to present to the examiner a clean set of claims which reflect all of the presently presented claim features.

During a telephonic interview between the undersigned attorney and the examiner on July 12, 2007, the various rejections of the claims were discussed with respect to the present invention and the cited prior art references. A summary of the telephonic interview is presented below.

In the office action of 4/17/07, claims 5-15 were rejected by the examiner under 35 U.S.C. § 102 and/or 35 U.S.C. § 103. The primary references used by the examiner in rejecting the claims were Schmidt (US 4,600,008), and Pilmanis (US 5,810,862).

On page 3 of the office action , the examiner states claims 5, 6, 8-11 and 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schmidt (4,600,008). This rejection is respectfully traversed.

The examiner states Figures 7-9 of Schmidt discloses component 54, which, according to the examiner is inherently capable of making a mark on a lens capsule by pressing on it to make a physical impression or indentation on it. Additionally, the examiner states that Schmidt discloses a delivery mechanism 52, 48 which is inherently capable of being inserted into an anterior chamber of an eye (when the component 54 is retracted therein as shown in figure 9). Applicant respectfully disagrees for at least the following reasons below.

First, as noted in paragraph [0005] of the present application, conventional techniques of performing an anterior capsulorhexis surgery procedures have involved manual estimation by the surgeon wherein the surgeon manually estimates the location, shape, and size of the intended capsulorhexis without the aid of any guide or reference mark on the lens capsule.

In contrast, as noted, for example, in paragraph [0018] of the specification of the present application (as published in Pub No. US 2004/0106929 A1), one novel and inventive aspect of at least one embodiment of the present relates to the creation and/or use of a physical mark or impression on the lens capsule of the eye to function as a reference template for facilitating the surgeon in performing a capsulorhexis procedure. In one embodiment, the size and shape of the mark corresponds to size and shape of the intended capsulorhexis. By creating a physical

impression on the capsule at the desired position of the lens capsule, the surgeon has a relatively fixed positional template or point of reference for performing the capsulorhexis, which can significantly aid the surgeon in performing a capsulorhexis procedure, particularly in situations where the eye moves during the surgery.

In at least one embodiment described in the present application, the marking component may be composed of a deformable and malleable material such as stainless steel or titanium, and may be formed in the shape of a circular or elliptical loop (see e.g., [0016]). In one embodiment, the marking component may be inserted into anterior chamber 304 of the eye through a small corneal incision, such as a standard cataract incision. (see e.g., [0023]) In at least one embodiment, a delivery mechanism may be used to deliver the marking component into the anterior chamber 304 of the eye through the small corneal incision.

Once the marking component has been delivered to the anterior chamber, the marking component may be used to physically touch the lens capsule thereby marking the capsule at a selected position with mark. In at least one embodiment, the mark may correspond to the size and shape of an intended capsulorhexis (as desired by the surgeon performing the surgery). In at least one embodiment, the marking component may include a dye for marking the lens capsule. (see e.g., [0017], [0023]). In at least one embodiment, the mark acts as a target or guide for the surgeon to follow in order to make a precise anterior capsulorhexis in accordance with a desired size/shape. (see e.g., [0023])

In contrast, the teachings of Schmidt are directed to an instrument for manipulating on the surface of the eye to remove foreign substances therefrom. (Schmidt, Abstract). It is submitted that there is no teaching or suggestion in Schmidt which would motivate one having ordinary skill in the art to use the device of Schmidt to facilitate implementation of a capsulotomy procedure.

As disclosed in Schmidt, the instrument of Schmidt includes a portion of a relatively thin, sterile, flexible thread-like member extending from at least one end thereof, the flexible thread-like member being shaped in the form of a loop and being adaptable for being placed on the surface of the eye between the eyeball and the underside portion of the eyelid. The loop portion of the thread-like member is adjustable to accommodate different areas of the eye surface and the present instrument is used mainly to remove foreign substances located on both the surface of the eye and the underside portion of the eyelid. (Schmidt 1:5-18)

The thread-like member 18 is preferably made from a relatively thin, flexible material such as from a fine gauge surgical suturing material having a flexural rigidity sufficient to maintain the portions 20 and 22 in looped fashion extending from both opposite ends of the

member 12. The material comprising the member 18 should be coarse enough to engage foreign bodies such as particles of dirt or sand on the eye surface when moved thereacross yet sufficiently smooth so as not to scratch, scar or otherwise damage the eye surface. This is important because the loop portions 20 and 22 of the thread-like member 18 are the portions that will be placed against and moved across the surface of the eye when removing foreign debris therefrom. It is also important that the material selected for the member 18 be soft and flexible enough to conform to the shape of the eye when inserted between the eye surface and the eyelid and that said material be sanitary and non-toxic so as not to cause inflammation and/or infection of the eye in which it comes in contact. Although it is generally preferred that the member 18 be made from certain gauges of extremely fine, sterile suturing material, it is also recognized that other suitable materials such as certain nylon and polyproplyene type materials, horse hair and human hair can be sterilized and used. (Schmidt 4:45-5:2, emphasis added)

It is noted that independent claim 16 defines a tool for facilitating implementation of a capsulotomy procedure which includes, among other things, a marking component comprised of a metal material. However, as discussed during a telephonic interview, it is submitted that Schmidt does not teach or suggest the desirability of a thread-like member 18 which is comprised of metal. In fact, Smith clearly teaches away from such a feature since, for example, the use of a metal material for thread-like member 18 may result in scratching, scaring, and/or other damage to the eye when the thread-like member 18 is used according to the teachings of Schmidt. Accordingly, for at least these reasons, independent claim 16 is believed to be unanticipated and unobvious in view of Schmidt.

It is also noted that independent claim 34 defines a tool for facilitating implementation of a capsulotomy procedure which includes, among other things, a marking component, and a dye or stain component, applyable to the marking component, and usable to make the mark on the lens capsule. As discussed during a telephonic interview, it is submitted that Schmidt does not teach or suggest the use of a dye or stain component which is applied to or applyable to thread-like member 18. Accordingly, for at least these reasons, independent claim 34 is believed to be unanticipated and unobvious in view of Schmidt.

On page 3 of the office action, the examiner states that the thread-like member of Schmidt is inherently capable of making a mark on a lens capsule by pressing on it to make a physical impression or indentation on it. Applicant respectfully disagrees, and respectfully asserts that the examiner's interpretation of the inherent teachings of Schmidt do not comply with MPEP 2112, Section IV. More specifically, MPEP 2112, Section IV states (in part):

...The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)...In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)... "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(Emphasis Original)...

In the present case, Schmidt explicitly teaches that the material comprising the member 18 should be sufficiently smooth so as not to scratch, scar or otherwise damage the eye surface, and further should be soft and flexible enough to conform to the shape of the eye when inserted between the eye surface and the eyelid. Although the examiner speculates that it *may* be possible to use the thread-like member to create a physical impression or indentation on the lens capsule of the eye, such a proposed characteristic does not necessarily flow from the teachings of Schmidt. Accordingly, it is respectfully asserted that the examiner has not established a prima facie case of inherency in accordance with MPEP 2112, Section IV since, for example, the examiner has not provided a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic(s) of Schmidt (as interpreted by the examiner) necessarily flow from the teachings of Schmidt.

On page 4 of the office action, the examiner states that Claims 5, 7 and 9 are rejected under 35 USC 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pilmanis (5,810,862). This rejection is respectfully traversed.

The examiner states that Pilmanis discloses marking component 16 which, according to the examiner, is inherently capable of making a mark on a lens capsule, and which is configurable to a desired shape and size during its assembly, depending on the number of needles 17 which are selected (citing Pilmanis col. 2, lines 24-35). Applicant respectfully disagrees.

The teachings of Pilmanis are directed to an instrument for the intradermal injection of liquid pigments which includes a needle assembly consisting of a number of needles, and a mass of solidified glue formed at one end of the needles to hold them in a predetermined relationship with one another and with their free ends projecting from the solidified glue at the opposite end. (Pilmanis, Abstract). The needle assembly of Pilmanis includes a needle bar 16 capable of holding and aligning a selected number of needles 17 so that the needles are positioned adjacent to one another in a planar array. Not only are the teachings of Pilmanis directed to non-analogous art, it is respectfully submitted that one having ordinary skill in the art would not be motivated to use the intradermal injection instrument of Pilmanis for facilitating implementation of a capsulotomy procedure. For example, the needle array 17 of Pilmanis would be undesirable for use in ocular surgery since one or more of the needles could potentially damage the eye cornea and/or lens capsule. Additionally, there is no teaching or suggestion in Pilmanis which supports the examiner's assertion in that the needle bar 16 is configurable to a desired shape and size corresponding to a desired capsulorhexis.

Additionally, it is noted that independent claims 16 and 34 each define a respective tool for facilitating implementation of a capsulotomy procedure which include, among other things, a marking component having an associated size which is adjustable by the user. For example, in at least one embodiment, the marking component may be configured by a user (e.g., a surgeon) a desired shape and size corresponding to the shape and size of an intended capsulorhexis. In at least one embodiment, the marking component may be composed of a deformable and/or malleable material to allow the size and/or shape of the marking component to be adjusted by the user (see, e.g., [0016]).

In contrast, it is submitted that Pilmanis does not teach or suggest a marking component (e.g., planar needle array 17) which allows for its size to be adjusted by the user, after the instrument has been assembled.

Additionally, it is noted that independent claims 16 and 34 each further define a delivery mechanism for delivering the marking component to the eye lens capsule, wherein the delivery mechanism is sized and dimensioned for insertion into an anterior chamber of the eye.

On page 4 of the office action, the examiner suggests that Pilmanis teaches a delivery mechanism 12 which is inherently capable of being inserted into an anterior chamber of the eye. Applicant respectfully disagrees, and respectfully asserts that the examiner has not established a prima facie case of inherency in accordance with MPEP 2112, Section IV since, for example, the examiner has not provided a basis in fact and/or technical reasoning to reasonably support the

determination that Pilmanis inherently teaches that grip member 12 is specifically sized and dimensioned for insertion into an anterior chamber of the eye.

Further, it is believed that neither Schmidt nor Pilmanis provide any teaching or suggestion which would motivate one having ordinary skill in the art to insert either of the devices of Schmidt or Pilmanis into the anterior chamber of the eye.

The additional limitations recited in the independent claims or the dependent claims are not further discussed as the above-discussed limitations are clearly sufficient to distinguish the claimed invention from Schmidt and/or Pilmanis. Because claims 16-37 are believed to be allowable in their present form, many of the examiner's rejections in the Office Action have not been addressed in this response. However, applicant respectfully reserves the right to respond to one or more of the examiner's rejections in subsequent amendments should conditions arise warranting such responses.

Applicant believes that all pending claims are allowable and respectfully requests a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below.

Respectfully submitted,
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